

1964

the-counter drugs, in cooperation with the President's Special Adviser on Consumer Affairs, Mrs. Esther Peterson?

Observers have remarked that almost never is a consumer group—or a group health medical group—represented before FDA when new drug regulations are being negotiated. The consumer tends to be the little man who isn't there.

It is small wonder that the consumer has so often been forgotten by FDA when opposite viewpoints in the form of commercial pressures have poured in.

ADDITIONAL "MYTH" ABOUT DRUGS—THAT "DRUG SAFETY HAS BEEN ENTIRELY TAKEN CARE OF"

Mr. HUMPHREY. Mr. President, it will be recalled that in my article in the May 16, 1964, issue of the New Republic, I listed certain myths and certain rebuttal facts about Federal drug policies.

I ask unanimous consent that a brief statement about one additional myth—an important myth, widely promoted—be reprinted at this point.

There being no objection, the statement was ordered to be printed in the Record, as follows:

THE MYTH THAT BECAUSE ABSOLUTE SAFETY IN DRUGS IS IMPOSSIBLE, THE PROFESSION AND THE PUBLIC "CAN NOW SIT BACK AND RELAX"

One of the most widespread myths is that the profession and the public need have no further cause for concern about drug safety.

The myth is founded on a truth—everyone does rightly realize that absolute—I emphasize, absolute—safety in drugs is not possible. Therefore, "why worry," according to this myth.

The answer to the myth is that there is definitely real reason for continuing concern. The reason is that certain shocking facts have come to light, indicating that conditions have been terribly lax. Therefore, anyone who today views drug safety with apathy is allowing himself to be needlessly tranquilized.

It is a fact that no thinking person believes that it is possible to secure absolute safety in drugs. Every thinking person realizes there will always be some risk in new drugs.

But various sources seem to misuse this argument as a means to condition the public into accepting less than the best standards.

HALF-TRUTHS ABOUT POOR TESTING IN ANIMALS

Neither the Congress, the profession nor the public should allow themselves to be fooled. Those who would try to convince the public otherwise assert, factually, that "no matter how many animals you test a drug on, you cannot predict how human beings will react, particularly how large numbers of people will react."

Those facts are true, but they are only half-truths. The real fact is that some drugs were never tested on animals at all, or so few animals and so few species over so short a period of time—as to be in a certain sense, largely untested.

The public has now received confirmation from no less than the Commissioner of Food and Drugs that there are many drugs now on the market which were never tested at all in animals before being tested in humans. This confirmation was given in hearings of the House Government Operations Subcommittee headed by Congressman L. H. FOUNTAIN.

A further fact is that many drugs have been tested usually over brief periods—in inexpensive laboratory animals like rodents, but have never been tested thoroughly in more expensive animals more closely related physiologically to man—such as primates, including monkeys.

Consider that the MER-29 producer had boasted to FDA that it had tested the drug thoroughly over 19 months in "all of three" monkeys, with no serious side effects. Later it was discovered that even that boast was a fraud. But to test a drug in only 3 monkeys and then to proceed to put it into 400,000 human beings is hardly to be taking adequate advance precautions.

PLEAS OF VIRTUAL GUILT TO CRIMINAL CHARGES

The public has now learned, too, that not just civil laws but criminal laws have been violated by some drug scientists and companies. The drug company which produced MER-29 and three of its former scientists have pleaded nolo contendere to criminal charges on falsification of test evidence on the drug.

A Maryland physician who tested drugs for 25 companies and who received, reportedly, \$33,000 for such tests, has also pleaded "nolo contendere" to charges of fabricating certain test reports.

Two other physicians have filed affidavits of falsification on an over-the-counter drug, Regimen.

These instances were not sheer happenstance; they were not isolated "flukes"; they came about because of deep underlying conditions of laxity. Nobody knows how deep these conditions really run. Why? Because FDA has had neither the zeal nor the manpower nor the authority to investigate the underlying conditions thoroughly.

How, then, can we possibly accept the myth "that there is no cause for continuing concern"?

GRIM FACTS WE CANNOT IGNORE

How can we ignore the grim fact that, for years, some drug companies suppressed reports of hundreds of injuries associated with drugs?

How can we ignore the grim fact that no one really knows to this day how safe or unsafe some drugs are, since only perhaps 5 percent or 10 percent of drug injuries are ever published or otherwise reported?

Certainly, there is no cause for hysteria. But there is certainly cause for vigilance and for continued reform.

SEVERAL NEEDS REVEALED BY RECENT CORRESPONDENCE—ON PROTECTING RETARDED CHILDREN, ON IMPROVING RECORDS, AND CONDUCTING CONTROLLED STUDIES

Mr. HUMPHREY. Mr. President, earlier, I had mentioned some of the correspondence which I have recently conducted. Let me mention a few of the facts which this correspondence reveals:

(a) The need for a review of the manner in which experimental and other drugs have been given to children in institutions, particularly mentally retarded children. A splendid letter from the excellent voluntary health agency, the National Association for Retarded Children, attests to this need.

(b) The need for FDA to identify—permanently and irrevocably—many dangerous drugs on which the agency's records are hopelessly incomplete.

I cite one hazardous drug which caused paralysis and which was apparently slipped off the market without the company even bothering to inform FDA.

From 1955 to 1963, FDA's record on this drug was a total blank. Yet, the drug had caused many injuries and was never legally suspended or formally withdrawn from the market.

(c) The need for FDA to require controlled clinical studies, as prescribed in Public Law 87-781. One widely used drug—since withdrawn from the market—Parnate, was used by 2 million patients.

Only four controlled studies have ever been reported on it, and not one of these studied was reported before—I emphasize "before"—the drug went on the market.

This omission is not, unfortunately, unusual. FDA has for years ignored the absence of controlled clinical studies.

MY INTEREST IN PHARMACEUTICAL SCIENCE CONTINUES INDEFINITELY

Finally, I should like to make an additional point particularly clear. My own interest in the highest possible standards in pharmaceutical science does not end with the conclusion of our hearings.

I hope no one will be under the misapprehension that because our formal study is ending, that I, for one, will watch idly if administrative reforms in drug policy are stopped, or, what is worse, if someone tries to turn the hands of the clock back.

I hope, to, that some of the organizations from whom the subcommittee has been awaiting replies for some time to our frank questions will not be under the misapprehension that our interest in their answers has ended and that they need not reply.

APPROVAL OF PRESIDENTIAL INABILITY RESOLUTION

Mr. KEATING. Mr. President, today the Subcommittee on Constitutional Amendments unanimously approved our consensus proposal to fill vacancies in the Vice Presidency and to set up procedures on Presidential inability. I joined with great satisfaction in that action.

As is true of any consensus, the resolution in its present form—the form in which it will receive further consideration by the full Judiciary Committee—is the product of the give-and-take of compromise, much like the original Constitution itself.

Throughout the many years of my interest in these problems, it was obvious to me that we would get exactly nowhere if everyone insisted on his own brain-child solution. This is no area for pride of authorship or partisan controversy. Much as the water's edge must be the stopping place for partisan politics in the realm of foreign affairs, the President's sickbed is no place for legalistic bickering.

If the same spirit of genuine cooperation and free and frank interchange of ideas that prevailed in our subcommittee follows this resolution through the remaining steps of the constitutional amending process, we can expect final action to come early. A measure designed to avoid a constitutional crisis which would threaten the very foundations of our Government can come none too soon, in my judgment.

At the same time, I remain somewhat leery of freezing into the Constitution a hidebound set of procedures to govern Presidential inability. On this aspect of the subcommittee's consensus, I intend to push for a broader constitutional provision merely authorizing Congress to take action by statute. If a majority of the Senate should agree with me, other subcommittee members have agreed to abide by the result and support this

11712

CONGRESSIONAL RECORD — SENATE

May 27

alternative. I am grateful for this pledge of continued cooperation; and, in turn, I can pledge to the other Members my cooperation in supporting to the hilt the final product of our efforts.

TRIBUTE TO SENATOR DIRKSEN'S WORK IN THE FIELD OF CIVIL RIGHTS

Mr. KEATING. Mr. President, many publications have hailed the work done by the distinguished minority leader [Mr. DIRKSEN] in the field of civil rights and the great contribution he has made to this task. Senator DIRKSEN has acted as a national leader and statesman in searching for a workable consensus on the critically important civil rights bill. His efforts have improved the bill in many important respects and won increased bipartisan support and for the principle of equal constitutional rights and for the provisions of this particular bill. The Catholic Standard, published in Washington, D.C., has paid him a very fine and well deserved tribute. I ask unanimous consent that it be printed at this point in the Record.

There being no objection, the article was ordered to be printed in the Record, as follows:

[From the Catholic Standard, Washington, D.C., May 26, 1964]

DIRKSEN'S CIVIL RIGHTS WORK HAILED

A tribute to the role of Senator EVERETT M. DIRKSEN, of Illinois in the current congressional effort to enact civil rights legislation was paid last Friday by Father John F. Cronin, S.S., of the National Catholic Welfare Conference.

"When the Congress passes a strong and just civil rights bill, much of the credit must be given to Senator Dirksen," the priest said at a meeting of Catholic Interracial Councils from Washington, Montgomery County and Northern Virginia.

Referring to the Dirksen package amendments to the civil rights bill, the assistant director of the NCWC Social Action Department emphasized the value of the Senator's two main intentions.

"He tried, in the first place, to secure racial justice by good law, rather than by demonstrations and pressures. His second objective was to meet legitimate objections to the bill as passed by the House. In particular, he wanted State laws and commissions to have the first opportunity to settle disputes, provided that they were really seeking such aims."

Father Cronin further asserted: "Senator DIRKSEN has risen above partisan and sectional considerations and has sought the long-range welfare of the entire United States. Such an approach deserves to be called patriotic and statesmanlike. If, on deeper study, we find flaws in his proposals, these do not invalidate the merited tribute to his efforts."

THE WAR IN VIETNAM

Mr. CLARK. Mr. President, two of the most astute and well-informed correspondents presently writing about foreign affairs are Tom and Harle Dammann, who write for the Chicago American. Early this month, they dispatched from Hong Kong an article entitled "Our War in Vietnam—If We Pull the Plug, Reds Could Flood the World."

I ask unanimous consent that the article, which sustains the position of

the administration with respect to Vietnam, be printed in the Record.

There being no objection, the article was ordered to be printed in the Record, as follows:

OUR WAR IN VIETNAM—IF WE PULL THE PLUG, REDS COULD FLOOD THE WORLD

(By Tom and Harle Dammann)

HONG KONG—The Communist Chinese have more at stake in the South Vietnamese war than the United States, and that is what makes it vitally important for the United States to persist in its program for the support of South Vietnam.

That is the opinion of experts in this acute listening post.

This is inextricably involved in the Sino-Soviet dispute. The Soviets believe in co-existence and would prefer a negotiated settlement in southeast Asia, particularly in South Vietnam. They want to avoid war and are convinced Communist objectives can be attained without it.

The Chicomps argue that Communists must keep fighting, that they can only spread communism by force. They say to the Soviets that there is no reason to fear a nuclear war because atom bombs would accomplish little in the jungles and rice paddies of South Vietnam except to obliterate the very people the "American imperialists" are supporting, and because, if the Americans were to resort to nuclear weapons, world opinion would turn against them.

If the Chicomps succeed in forcing a U.S. withdrawal, they will not only seriously bloody the American image, they will upset Premier Nikita Khrushchev's policies and set the pattern for Communist aggression in Asia, Africa, and Latin America, over which Moscow and Peking already quarrel. In short, South Vietnam is the hot spot in the new cold war between the Soviets and Chinese Communists.

For our part, if we withdrew, we would lose what allies we have left in southeast Asia, notably Thailand and Malaysia, questionable nations like Laos would swing into the Peking orbit, and our influence in Japan and Formosa would diminish.

So Peking is steadily forcing the issue and almost welcomes the increase of American commitment in South Vietnam on the grounds that the higher we climb the harder we will fall.

In addition to the advantages the stealthy guerrilla has in any war, the Chicomps are banking on the fact that much of the Vietnamese population is fed up with wars, which have plagued it for 20 years almost without interruption.

But there is another side to the coin. As Peking steps up the pressure in its cold war with Moscow, it places its friends on the spot and even the Communist North Vietnamese are squirming, trying not to commit themselves too deeply to the Chicomps, whom they know have many serious, handicapping internal problems.

It is suggested, too, that recent events in Laos may reflect doubts that the South Vietnamese Communists, the Vietcong, can win against the great efforts of the South Vietnamese Government supported by the United States.

Certainly, when we talked a few days ago in Saigon with senior American diplomats, military officers, and the prime minister, Gen. Nguyen Khanh, we could detect no loss of confidence. Those authorities subscribe to the above analysis, but, as one of the most responsible officials told us privately, "I am guardedly optimistic for the first time."

"The American people must appreciate that this is going to be a long, costly, and deadly process," this official warns. "First off, it is difficult to identify the enemy because Vietnamese are fighting Vietnamese. We our-

selves are at a disadvantage, for our troops are white or black, not yellow, which means we can't actually get into the guerrilla fighting and must support our friends in every other way conceivable.

"Another reason for our difficulties is that we have gone through a period of 9 months of disruption by three coups. But now we have General Khanh as prime minister and he is a dedicated citizen trying to make the common folk understand that his government is solidly behind them, and that the war is in the country, not in the bars of Saigon.

"Still another problem is that there is no real sense of unity in this country of diverse religions, ethnic groups, and tribes. The family is the real unity. The army suffers many desertions, but the deserters don't think they are being disloyal to their country for they have merely gone home to see their family, to learn whether they can help with planting or harvesting," the officer continued.

"This war is primarily not a military operation: It is civil and psychological," he emphasized. "We are concentrating on training civil servants so that they can go into the country and take on responsible jobs as we gain security.

"We are impressing the Vietnamese army with necessity of training its troops to meet the civilian population with tact and friendliness and not rob them of their chickens and rice."

As for the 36-year-old Prime Minister, Khanh, who is fluent in French and English, he makes you believe him when he says he is going to bring free elections to his country soon. He has a confidence and sense of public relations which, given the opportunity, can win the people over.

"The average guy here wants to be safe at night, get an education, health, and decent price for his rice," a high-ranking diplomat commented. "If we can provide these, we will win." But, as Ambassador Henry Cabot Lodge has said, "we will have to exercise greater perseverance and patience than we are accustomed to."

"The important thing is that the Communist Chinese have chosen the battleground. If we let them have it, we lose southeast Asia, and their self-confidence will become the most dangerous threat to human life existent. We have to stay and win, for the sake of the entire free world," he concluded.

MESSAGE FROM PRESIDENT JOHNSON, ADDRESS BY MAYOR WILLY BRANDT, AND RESOLUTIONS AT 17TH ANNUAL CONVENTION OF AMERICANS FOR DEMOCRATIC ACTION

Mr. CLARK. Mr. President, last week, Americans for Democratic Action held their 17th annual convention in Washington, D.C. They received from the President of the United States a most cordial message in which he asked for the help of the ADA in connection with his domestic programs and his foreign program. They also heard an inspiring address by Willy Brandt, the mayor of Berlin; and they adopted a number of resolutions dealing with matters of considerable interest to the Congress.

As a member of the national board of directors of the ADA, I ask unanimous consent that the President's message, Mayor Willy Brandt's speech, and the resolutions be printed in the Record, in connection with my remarks.